Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: **Zelnorm® (Tegaserod Maleate)**
Date: **July 27, 2005**
Prepared for:
Prepared by: **Missouri Medicaid**

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: To control evaluate, monitor and promote prudent prescribing of Zelnorm with regards to indication and duration of use.

Why was this Issue Selected: Zelnorm offers a treatment modality for contstipation-predominant irritable bowel syndrome (IBS) in women. It has demonstrated efficacy in a portion of patients receiving the drug in clinical trials and lacks significant drug interactions. Since IBS is a disease state normally exhibiting symptomatic clusters, the expected usage patterns are not for ongoing chronic administration, but rather on a PRN basis, for exacerbations. In addition to the IBS indication, Zelnorm is now approved to treat chronic idiopathic constipation in patients less than 65 years of age.

Program-specific information:

Drug	AWP
• Zelnorm 2mg Tabs	*$172.74/month*
• Zelnorm 6mg Tabs	*$172.74/month*

Setting & Population: All patients

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Non-Preferred Agent**
☒ **Appropriate Utiliztion**

Data Sources:
☒ **Only administrative databases**
☐ **Databases + Prescriber-supplied**

Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria, which is different from prior authorization or prior approval programs, assist in the achievement of qualitative and economic goals related to health care resource utilization without placing the entire utilization of a drug in a PA status. Screening the use of certain medications on the basis of clinical appropriateness can reduce costs by requiring evidence of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Setting & Population

- Drug for review: Zelnorm®
- Gender: Male/Female

Approval Criteria

- Diagnosis of Irritable Bowel Syndrome
    - Female
    - Primary bowel symptom of constipation
    - Therapy approved for no more than 3 annual exacerbations (not to exceed 12 weeks per exacerbation)
    - Gastroenterologist consult may be required after 2 cycles
- **Diagnosis of Chronic Idiopathic Constipation**
    - **Patient must be less than 65 years old**
    - **Trial and failure on at least 1 OTC laxative**
    - **Trial and failure on at least 1 RX laxative**

Denial Criteria

- Lack of appropriate diagnostic evidence
- Therapy exceeding approval length

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐	Other:	☐

Disposition of Edit

- **Denial:** Edit 682 “Clinical Edit”

References

1. USPDI, Micromedex, 2005.
2. Evidence Based Medicine Analysis: “Zelnorm”, UMKC-DIC, January 2004.
3. Facts and Comparisons, p. 1165a – 1165b, 2005.
4. Novartis Pharmaceuticals Corp. East Hanover, New Jersey. “Zelnorm – Formulary Submission Dossier.” January 2005.